SEP 2 0 2001 K011988 1/2

510(k) Summary

Surgical Lightstic™ 180

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR §807 for the Surgical Lightstic™ 180.

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Joseph Curtis
10 Commerce Way
Norton, MA 02766
Telephone: (508) 285-1700
Facsimile: (508) 285-7579

Contact Person: same

Date Prepared: June 22, 2001

Name of Device and Name/Address of Sponsor

Surgical Lightstic™ 180
CardioFocus, Inc.
10 Commerce Way
Norton, MA 02766

Common or Usual Name

Laser Tissue Coagulator

Classification Name

Surgical Laser Instrument Accessories

Predicate Devices

The Surgical Lightstic 180 for use in cardiac tissue is identical to the current Surgical Lightstic 180 (K993834), and substantially equivalent for indications for use in cardiac tissue to Cryomedical Sciences, Inc. CMS Blizzard K980668 .

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Intended Use

The Surgical Lightstic™ 180 is intended to be used as a surgical instrument for coagulation of soft tissue (including cardiac tissue) in conjunction with or without endoscopic equipment (including laparoscopes, hysteroscopes, bronchoscopes, cystoscopes, gastroscopes, colonoscopes), in the contact or non-contact mode in both open or closed surgical procedures (with or without handpiece).

The Surgical Lightstic™ 180 is indicated for use in laser medicine and surgery with 980-1064 nm wavelength laser energy in the following surgical specialties: general surgery, cardiothoracic surgery(recommended 980nm), plastic surgery and dermatology.

Technological Characteristics and Substantial Equivalence

From a clinical perspective and comparing design specifications, the CardioFocus Surgical Lightstic™ 180 and the predicate device are substantially equivalent and have the same intended use.

CardioFocus, Inc. believes the minor differences of the CardioFocus Surgical Lightstic™ 180 and its predicate fiber laser accessories should not raise any concerns regarding the overall safety and effectiveness.

Performance Data

None required.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2008

CardioFocus, Inc.
c/o Mr. Joseph Curtis
Vice President Clinical and Regulatory Aff airs
10 Commerce Way
Norton, MA 02766

Re: K011988
Trade/Device Name: Surgical Lightstic ™ 180
Regulation Number: 21 CFR 878.4810
Regulation name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II (two)
Product Code: OCL
Dated: June 25, 2001
Received: June 26, 2001

Dear Mr. Curtis:

This letter corrects our substantially equivalent letter of September 20, 2001.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

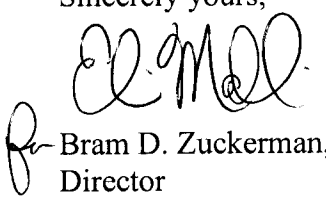
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K011988

Device Name: Surgical Lightstic™ 180

Indications For Use: Expanded for: Coagulation of Cardiac Tissue

Note: These are additional indications to the already cleared indications for market release in K993834.

_____ _____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR §801.109)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011988